# IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Kuijpers, et al.

Examiner: Nolan, P.

Serial No.: Unassigned

Group Art Unit: 1644

Filed: Herewith

Docket: 294-70 CON

For: TREATMENT OF OCULAR

Docker. 294-70 CON

DISORDERS

Dated: February 19, 2002

EXPRESS MAIL CERTIFICATE

Assistant Commissioner for Patents Washington, DC 20231 Date 2-19-02 Label No £ L709 ((4239 4) I hereby certify that on the date indicated above, I deposited this paper or fee with the U.S. Postal Service & that it was addressed for delivery to the Assistant

CUSTA A.S.

PRELIMINARY AMENDMEN Viring (Print)

Sir

Applicants respectfully submit the following Preliminary Amendment for entry in the above-identified application prior to examination.

## IN THE SPECIFICATION:

On page 1, after the title, before line 1, please insert:

This application is a continuation of U.S. Application Serial No. 09/258,240, filed on February 26, 1999, pending. The entire disclosure of the aforementioned application is incorporated herein by reference.

#### IN THE CLAIMS:

Please cancel Claims 1-9.

Please add new Claims 10-18 as follows:

10. (New) A method for the treatment of an ocular disorder comprising administering an octreotide to a patient, wherein said octreotide binds to at least one somatostatin receptor in the eye, and wherein said ocular disorder is selected from the group consisting of retinal edema, macular edema, age related macular degeneration and central serous chorio-retinopathy.

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- (New) The method of Claim 10, wherein said octreotide is administered topically.
- (New) The method of Claim 11, wherein said octreotide is administered in the form of an ophthalmic liquid preparation.
- (New) The method of Claim 10, wherein said octreotide is administered subcutaneously.
- 14. (New) A method for the topical treatment of macular edema comprising topically administering to a patient a somatostatin analog which binds to at least one somatostatin receptor in the eye, wherein said somatostatin analog is a polypeptide, and wherein said somatostatin analog is in the form of an ophthalmic liquid preparation.
- (New) The method of Claim 14, wherein said ophthalmic liquid preparation is in the form of eye drops, an eye gel or an eye ointment.
- (New) The method of Claim 14, wherein said somatostatin receptor is an hSST-2 receptor.
- 17. (New) The method of Claim 14 wherein the somatostatin analog is an octreotide.
- 18. (New) A method for the topical treatment of diabetic retinopathy comprising topically administering to a patient an octreotide, wherein the octreotide binds to at least one somatostatin receptor in the eye, and wherein the octreotide is in the form of an ophthalmic liquid preparation.

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#### REMARKS

Claims 1-9 have been cancelled, and new Claims 10-18 have been added. Accordingly, Claims 10-18 are pending.

Before the present invention, diabetic retinopathy was treated by inhibiting the secretion of growth hormone by the pituitary gland. Such treatment required systemic administration of a compound to block the somatostatin receptors in the pituitary gland, or surgical removal of the pituitary gland.

Applicants have made the surprising discovery that somatostatin receptors are expressed in the eye. Additionally, Applicants have discovered that since somatostatin analogs bind to these receptors in the eye, these analogs can be used to treat ocular disorders, such as diabetic retinopathy and macula edema.

Support for the pending claims is found throughout the specification as filed. No new matter has been added.

Applicants respectfully submit that the application, including Claims 10-18, is now in condition for allowance, which action is earnestly solicited. If resolution of any remaining issue is required prior to allowance of this application, it is respectfully requested that the Examiner contact Applicants' undersigned attorney at the telephone number provided below.

Respectfully submitted,

Susan A. Sipos

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## VERSION OF AMENDMENT WITH MARKINGS TO SHOW CHANGES MADE

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## IN THE CLAIMS:

Please cancel Claims 1-9.

Please add new Claims 10-18 as follows:

- 10 (New) A method for the treatment of an ocular disorder comprising administering an octreotide to a patient, wherein said octreotide binds to at least one somatostatin receptor in the eye, and wherein said ocular disorder is selected from the group consisting of retinal edema, macular edema, age related macular degeneration and central serous chorio-retinopathy.
- (New) The method of Claim 10, wherein said octreotide is administered 11. topically.
- 12. (New) The method of Claim 11, wherein said octreotide is administered in the form of an ophthalmic liquid preparation.
- 13. (New) The method of Claim 10, wherein said octreotide is administered subcutaneously.

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- 14. (New) A method for the topical treatment of macular edema comprising topically administering to a patient a somatostatin analog which binds to at least one somatostatin receptor in the eye, wherein said somatostatin analog is a polypeptide, and wherein said somatostatin analog is in the form of an ophthalmic liquid preparation.
- 15. (New) The method of Claim 14, wherein said ophthalmic liquid preparation is in the form of eye drops, an eye gel or an eye ointment.
- (New) The method of Claim 14, wherein said somatostatin receptor is an hSST-2 receptor.
- (New) The method of Claim 14 wherein the somatostatin analog is an octreotide.
- 18. (New) A method for the topical treatment of diabetic retinopathy comprising topically administering to a patient an octreotide, wherein the octreotide binds to at least one somatostatin receptor in the eye, and wherein the octreotide is in the form of an ophthalmic liquid preparation.